UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN, *ex rel.* DAVID KESTER, Plaintiffs and Relator, -against- NOVARTIS PHARMACEUTICALS CORPORATION Defendant.	**11 CIV. 8196 (CM) (JCF)**

NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO COMPEL FURTHER DISCOVERY RESPONSES FROM THE UNITED STATES AND FROM THE STATES OF CALIFORNIA, GEORGIA, ILLINOIS, INDIANA, MARYLAND, MICHIGAN, NEW JERSEY, NEW YORK, OKLAHOMA, WASHINGTON AND WISCONSIN

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Pursuant to Rule 37 of the Federal Rules of Civil Procedure and Rules 7 and 37 of the Local Rules for the Southern District of New York, Defendant Novartis Pharmaceuticals Corporation ("NPC") respectfully submits this memorandum of law in support of its motion to compel the United States (the "U.S.") and the States of California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, Washington, and Wisconsin (collectively, the "States" and, with the U.S., the "Government") to produce discovery relating to: (i) medication adherence programs and initiatives by the Government; (ii) immunosuppressive therapies for kidney transplant patients and iron chelation therapy at Government hospitals and healthcare facilities; and (iii) settlement communications between the Government and BioScrip relating to BioScrip's stipulation of facts.

PRELIMINARY STATEMENT

This case is an attempt by the Government to impose significant civil liability on NPC pursuant to the federal False Claims Act, 31 U.S.C. § 3729 ("FCA") and its state law counterparts. The alleged false claims are predicated upon purported violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"). Specifically, the Government seeks to label certain discounts, rebates, and medication adherence-related incentives NPC provided to specialty pharmacies as "kickbacks" that resulted in the submission of "tens of thousands" of false claims to Medicare and Medicaid. The Government contends that NPC engaged in two different kickback "schemes":

The first alleged scheme concerns Exjade®, a once-a-day oral medication that removes excess iron from the blood that can build up in patients who require frequent blood transfusions or have a non-transfusion-dependent blood disorder. NPC distributed Exjade primarily through a network of three specialty pharmacies. One of those pharmacies was then co-defendant BioScrip. The Government contends that NPC's discounts, rebates, and allocations of Exjade

prescriptions to BioScrip became illegal kickbacks when, in February 2007, BioScrip increased its patient outreach and refill reminder services to improve medication adherence among its Exjade patients.

The second alleged scheme concerns Myfortic®, an immunosuppressant prescribed to prevent organ rejection in kidney transplant recipients. The U.S. (the States did not intervene as to Myfortic) alleges that market share rebates NPC paid to certain specialty pharmacies violate the AKS. Although the U.S. appears to acknowledge that NPC's market share rebate contracts are legal, the U.S. contends that the rebates somehow became illegal kickbacks when the specialty pharmacies agreed to influence doctors to "switch" patients to Myfortic from a competing immunosuppressant, CellCept, and/or generic forms of CellCept, or maintain patients on Myfortic instead of the alternative immunosuppressant treatment on the basis of "pretext[ual]" clinical information. Ex. B[1] at 8:21-9:3; *see also* Second Amended Complaint-in-Intervention of the U.S., Dkt. No. 231 ("Second Am. Compl.") ¶ 6 ("[H]undreds, possibly thousands, of transplant patients have undergone switches in their medication as a result of recommendations from pharmacies that were based on undisclosed financial, rather than independent clinical, considerations.").

NPC contends that its rebates, discounts, and medication adherence-related incentives do not violate the AKS or FCA and that, contrary to the Government's allegations, these incentives have not resulted in improper Exjade adherence initiatives or pretextual conversions to Myfortic. Indeed, the Government itself promotes medication adherence programs and Government hospitals will likely have information regarding the clinical attributes of both drugs that pertain

[1] All references to "Ex." are to Exhibits to the Declaration of Manisha M. Sheth, filed concurrently herewith ("Sheth Decl."). The verbatim text of the discovery requests and responses at issue in this motion are set forth in full in Exhibit A to the Sheth Declaration.

to the validity of Exjade adherence efforts and clinical reasons for "switching" patients to Myfortic that the Government describes as "pretext." Although the information NPC seeks from the Government is relevant to the Government's claims and allegations, the Government has refused to produce such evidence, necessitating this motion.

This motion seeks an order compelling the Government to produce three categories of documents: First, this motion seeks documents relating to the Government's own adherence programs and initiatives. Given the Government's allegations that the Exjade adherence initiatives at issue in this case were improper, NPC is entitled to discovery regarding the contours of what the Government deems a proper adherence initiative (as it presumably regards its own). Second, this motion seeks documents related to immunosuppressive therapies for kidney transplant patients and iron chelation therapies at Government medical facilities. Here too, NPC should be permitted to test the Government's allegations that NPC's rebates and discounts led to the conversion of patients to Myfortic for pretextual clinical reasons or caused patients to continue taking Exjade contrary to the clinical advice of their prescribing physicians on the recommendation of allegedly underqualified and undertrained BioScrip employees. If Government-authored medication protocols or other documents reflect the same clinical considerations flagged by specialty pharmacies, confirm that Exjade should be taken consistently and not on an as-needed basis as the Government has argued, or endorse BioScrip as a qualified or even preferred Exjade provider, these documents are relevant to assessing the validity of the Government's contentions.

Third, this motion seeks communications between the Government and BioScrip relating to a series of facts to which BioScrip stipulated as part of its settlement with the Government. The Government has repeatedly invoked these "facts" in setting forth its case against NPC at

court conferences and in press releases. There can be no serious dispute that communications between the Government and BioScrip about these facts are relevant. Nor can there be any argument that these communications are shielded from discovery by any privilege. The settlement privilege—to the extent it might apply—affects at most their admissibility at trial and any attorney-client or work product protections were waived when the communications were shared between the Government and BioScrip.

The Government's refusal to provide these three categories of discovery that are relevant (and potentially highly relevant) to the Government's claims and allegations is improper, and prejudices NPC's ability to prepare its case in response to such allegations. The Government should be compelled to provide complete discovery responses and produce all non-privileged documents responsive to the discovery requests identified herein without further delay.

RELEVANT LEGAL AND FACTUAL BACKGROUND

The AKS. The AKS makes it illegal to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate)" to any person to induce that person to "purchase . . . order . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Relevant to the allegations in this lawsuit, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g).

The Department of Justice ("DOJ") has stated that the AKS is "intended to ensure that a physician's medical judgment is not compromised by improper financial incentives and is instead based on the best interests of the patient." *See* Ex. C. Notably, not all payments or incentives from a pharmaceutical manufacturer to a healthcare provider ("HCP") are prohibited

by the AKS. Indeed, the first exception Congress made to the broad sweep of the AKS was for discounts and price reductions to HCPs. Pursuant to the statutory exception, the AKS:

> [s]hall not apply to a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction of price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(3)(A). The corresponding discount safe harbor regulation at 42 C.F.R. § 1001.952(h)(4) makes clear that permissible discounts may take the form of rebates.

The NPC Medications at Issue. NPC researches, develops, manufactures and markets innovative prescription medicines. One of those medicines is Exjade (deferasirox), an oral medication that is indicated for the treatment of chronic iron overload resulting from blood transfusions. *See, e.g.*, Second Am. Compl. ¶ 231. Chronic iron overload is a dangerous condition that, if left untreated, can ultimately be fatal. *See id.* Although chelation therapy, including Exjade, is critical to the patient's health, compliance with such therapy is challenging because, among other things, it may take some time for a patient to feel the benefit of treatment. *See* Ex. D, John Porter et al., "The challenges of adherence and persistence with iron chelation therapy," 94 Int'l J. of Hematology 453, 454-455 (2011).

The other medication at issue, Myfortic (mycophenolic acid), is prescribed to kidney transplant patients to help prevent organ rejection by suppressing the body's immune response. Second Am. Compl. ¶ 119. The alternative immunosuppressant in Myfortic's class of medications is CellCept, sold in branded form by F. Hoffman-LaRoche Ltd., and in generic forms (mycophenolate mofetil or "MMF") since 2009. *Id.* ¶ 122.

Specialty Pharmacies. The pharmacies involved in this case are primarily "specialty pharmacies." Specialty pharmacies are full service pharmacies that specialize in dispensing specialty medications that treat complex conditions including multiple sclerosis, certain cancers,

solid organ transplant, and hemophilia, and "typically require special handling and other specialty expertise." *See, e.g.*, Ex. E. The distribution of Exjade is largely coordinated through a single point of contact called Exjade Patient Assistance & Support Services ("EPASS") that receives prescriptions for new Exjade patients and conducts an initial benefits investigation to evaluate patients' insurance coverage for the product. For much of the time period relevant to the litigation, EPASS sent the Exjade prescription to one of three specialty pharmacies in the EPASS distribution network, one of which was BioScrip, the settling co-defendant named in the Government's complaints. *See, e.g.*, Second Am. Compl. ¶ 241. The specialty pharmacies dispense Exjade to patients, contact them about refills, and provide patient education and counseling. *Id.* ¶¶ 241, 243-44.

NPC distributes Myfortic through many pharmacies across the United States, including various specialty pharmacies that have market share rebate agreements with NPC. *See id.* ¶¶ 140-41, 145.

This Lawsuit and the Government's Extensive Pre-Intervention Investigation. In November 2011, Relator David Kester, then a Sales Manager for NPC's cystic fibrosis medicine TOBI, initiated this case by filing a *qui tam* suit under seal. Following the filing of the *qui tam* suit, the Government conducted an extensive investigation of NPC's relationships with specialty pharmacies regarding the dispensing of Exjade, Myfortic, and three other medications. In the course of its lengthy investigation, the Government issued over fifty civil investigative demands, obtained more than 15 million pages of documents from NPC, pharmacies, and hospitals, and deposed and interviewed numerous NPC and pharmacy employees. In addition, the Government had access to its own data on claims reimbursed by government healthcare programs including Medicare and Medicaid. The U.S. intervened as to the Relator's allegations concerning Myfortic

and filed its original complaint in intervention on April 23, 2013. On January 8, 2014, the U.S. amended its complaint, adding allegations related to Exjade and naming BioScrip as a co-defendant. On the same day, the States, except for Washington, also filed complaints against NPC and BioScrip relating to Exjade only. Dkt. Nos. 60, 61. Washington filed its complaint on January 27, 2014. Dkt. No. 82. On August 28, 2014, the U.S. filed a Second Amended Complaint-in-Intervention. Dkt. No. 231.

The Exjade Allegations. The Government alleges that from February 2007 to May 2012 NPC paid kickbacks to BioScrip in exchange for which BioScrip engaged in "intensive" adherence-related efforts—namely, encouraging patients to order their doctor-prescribed Exjade refills and/or resume doctor-prescribed Exjade therapy that they had discontinued. Second Am. Compl. ¶ 302. These alleged kickbacks took the form of contractual discounts and rebates, as well as the allocation of additional patients to BioScrip when BioScrip showed improvement in patient adherence. *Id.* ¶¶ 303-04.

NPC first contracted with BioScrip to dispense Exjade in 2005, at which time it provided discounts to BioScrip under an agreement that also provided that BioScrip would contact patients about refills, provide patient education and ship Exjade to patients, among other activities. *Id.* ¶¶ 242-44. The Government does not allege that the discounts paid beginning in 2005 violated the AKS or the FCA. Rather, the Government contends that a "threat" by NPC in February 2007 to reconsider whether BioScrip should be part of EPASS because its refill levels were below those of the other two EPASS pharmacies transformed BioScrip's patient outreach calls and refill reminders into improper activity and NPC's discounts into purported "kickbacks." *Id.* ¶¶ 253-58. The Government contends that after 2007 BioScrip used insufficiently trained and unqualified personnel to call patients, *id.* ¶ 284, and prompted patients to order refills of Exjade

that were not "needed or clinically appropriate," *id.* ¶ 274. This conduct, according to the Government, resulted in the submission of "tens of thousands of false claims to Medicare and Medicaid." *Id.* ¶ 311.

The Myfortic Allegations. The U.S. also alleges that discounts and market share rebates NPC paid to "twenty-some" pharmacies based on their purchases of Myfortic constitute kickbacks in violation of the AKS because of alleged extra-contractual side agreements between NPC and the pharmacies. *Id.* ¶¶ 141, 146, 207. The U.S. contends that "agreements" outside the four corners of the written contracts, through which the pharmacies supposedly "committed" to NPC that they would encourage doctors to "switch" patients to Myfortic from CellCept and "prevent" those doctors from using generic CellCept, transformed otherwise-legal contractual discounts and rebates into illegal kickbacks. *Id.* ¶¶ 5, 141-47. Despite its broad allegation that NPC paid Myfortic-related kickbacks to "twenty-some" specialty pharmacies, the U.S. has alleged the particulars of supposed side agreements with only five. *See id.* ¶¶ 151-201. As with Exjade, the U.S. alleges that these "agreements" collectively resulted in "tens of thousands" of false claims. *Id.* ¶ 221.[2]

[2] There are no allegations in this case that NPC engaged in off-label promotion or made improper payments to doctors with respect to either drug. Nor are there any allegations that any discounts or rebates that NPC paid to any specialty pharmacy were not disclosed or passed on to the Government.

ARGUMENT

I. THE GOVERNMENT SHOULD BE ORDERED TO PRODUCE DOCUMENTS RELATING TO ITS MEDICATION ADHERENCE PROGRAMS AND INITIATIVES

A. The Requested Adherence-Related Discovery Is Relevant To The Claims And Defenses In This Case

To prove its claims as alleged under the federal and state FCAs, the Government must show that NPC's rebates and adherence programs crossed the line between legal conduct that legislators and regulators encourage, on the one hand, and illegal conduct actionable under the AKS on the other. However, NPC believes the Government promotes conduct that is substantially the same as the conduct it seeks to penalize here. For example, the federal government actively encourages medication adherence—by, among other things, promoting refill reminder programs and offering financial incentives to Medicare Part D plan sponsors for achieving certain adherence goals—recognizing that when patients adhere to their prescribed medication therapies it benefits both patient health and the public fisc by reducing medical services expenditures.[3] The States have similar programs.[4]

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[3] *See, e.g.*, Ex. F, Daniella Perlroth, *et al.*, *Medication Therapy Management in Chronically Ill Populations: Final Report Prepared for Centers for Medicare & Medicaid Services (CMS)* (Aug. 2013), at 3, available at http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf ("Poor medication adherence has been associated with adverse health outcomes and increased risk of mortality across multiple disease conditions, particularly among patients with chronic conditions. Medication non-adherence accounted for 33%-69% of all medication-related hospital admissions in the U.S. in 2000. The cost of medication non-adherence was estimated to exceed $177 billion, with medication-related hospitalizations accounting for almost 70% ($121.5 billion) of that estimate (2000 U.S. dollars).") (citations omitted).

[4] *See, e.g.*, Ex. G, James J. Figge, M.D., State of N.Y. Dep't of Health, *NYS Medicaid E-Prescribing Incentive Program: Interface with HITECH and Meaningful Use* (May 2010), at 13 (New York conditions e-prescription incentives on patient *collection* of medication to "[i]ncentivize[] . . . promotion of patient medication adherence"), *available at* http://www.health.ny.gov/regulations/arra/docs/ nys_medicaid_e-prescribing_incentive.pdf; Ex. H, Md. Dep't of Health and Mental Hygiene, *Maryland P3 (Patients, Pharmacists,*

In order to defend itself against the Government's claims that NPC sponsored illegal rebate and adherence programs, NPC seeks documents and information concerning the Government's own rebate and adherence programs—programs the Government presumably regards as proper and legal. In particular, NPC's Requests for Production ("RFP") Nos. 71-73, 75-82, and 89-92 to the U.S. seek documents relating to the U.S.'s own initiatives to promote medication adherence, including documents regarding:

- Adherence-related components or requirements of certain federal health-related programs and grants, and other federal adherence-related policies, activities, programs, plans, or initiatives (RFP Nos. 71-73, 80, 82, 89, 90, 92);
- The U.S.'s exclusion of communications encompassing adherence-related communications from the definition of "marketing" in certain laws and regulations and its publication regarding refill reminders (RFP Nos. 75-78); and
- The U.S.'s report regarding the budgetary impact of medication adherence and other documents regarding the savings, costs, and/or patient outcomes associated with medication adherence (RFP Nos. 79, 81, 91).

Ex. I at Nos. 71-73, 75-82; Ex. J at Nos. 89-92. NPC directed similar requests to the States. *See* Exs. K-U at Nos. 36, 38-39; Ex. V at No. 50. The Government refuses to produce documents responsive to these Requests and incorrectly asserts that the discovery sought is not relevant. *See* Ex. W at Nos. 71-73, 75-82; Ex. X at Nos. 89-92 ; Ex. Y at 3-5; Ex. Z at 3; Ex. BB & CC at Nos. 36, 38-39 ; Ex. DD at No. 50; Ex. EE at 4; Ex. FF at 2; Ex. GG.[5]

Partnerships) Program (Oct. 18, 2013) (describing state-sponsored program pairing patients with pharmacists who meet several times a year to improve medication adherence), *available* at http://dhmh.maryland.gov/ innovations/SitePages/maryland-p3-program.aspx.

[5] Following extensive meet and confer efforts, the States agreed to produce non-privileged documents in the possession, custody, and control of the States' Single State Agencies ("SSAs") that relate to Exjade adherence only. Ex. GG. The U.S. still refuses to produce any materials related to its adherence programs, arguing that such materials are not relevant because they are not public and therefore NPC had no "notice" of these programs. Sheth Decl. ¶ 37. This argument misses the point. NPC's defense is not that it modeled its adherence programs on the U.S. programs. Its defense is that its adherence programs were proper and consistent with industry standard, as made clear by the fact that the U.S. engages in substantially similar conduct.

Documents related to the Government's own adherence programs and initiatives are relevant to the appropriateness of the adherence programs at issue here. The Government does not merely enforce the law in this arena; it is also an active participant in it, formulating its own adherence initiatives to encourage medication compliance. What the Government deems appropriate and desirable in conducting its own affairs as a market participant is unquestionably relevant to whether it can deem similar conduct *illegal* when it dons its enforcement hat. If the Government's own programs encourage patients to adhere diligently to their iron chelation therapies rather than take their medication only on an "as needed" basis, that is relevant to the Government's and Relator's argument that BioScrip's patient outreach was improper for doing the same thing.

Moreover, documents evidencing the contours of the Government's own adherence programs are also relevant to establishing the reasonableness of NPC's conduct regarding the incentives at issue in this case. If NPC's allegedly illegal adherence programs resemble those the Government sponsors or otherwise sanctions, it would be compelling evidence that NPC's conduct was reasonable and cannot be a knowing and willful violation of the AKS and the FCA. *See, e.g.*, *U.S. ex rel. Finney v. Nextwave Telecom, Inc.*, 337 B.R. 479, 488 (S.D.N.Y. 2006) (McMahon, J.) ("'[U]nresolved disputes about the proper interpretation of a statute or regulation should not lead to suits under the FCA, at least where a claimant's interpretation of the governing law is reasonable.'") (quoting *Visiting Nurse Ass'n of Brooklyn v. Thompson,* 378 F. Supp. 2d 75, 96 (E.D.N.Y. 2004)). Given that the Government will have to establish that NPC "knowingly and willfully" offered illegal remuneration to BioScrip, *see* 42 U.S.C. § 1320a-7b(b)(2), the reasonableness of NPC's conduct will be a critical issue in this case.

Thus, the requested documents are relevant and should be produced absent some compelling objection. The Government offers none.

B. The Government Has Not Asserted Any Valid Objections To NPC's Requests

Aside from the Government's relevance objections, which are without merit for the reasons set forth above, the U.S. also argues that these documents are protected by the deliberative process privilege. *See* Ex. W at Nos. 71-73, 75-82; Ex. X at Nos. 89-92.[6] The States assert the additional objection that they are obligated to produce only documents within the custody, possession, or control of the Single State Agencies ("SSAs") charged with the administration of Medicaid in each State. Exs. BB & CC at Nos. 36, 38-39; Ex. DD at No. 50. Neither of these objections has merit.

1. The Deliberative Process Does Not Apply

"The deliberative process privilege 'covers documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.'" *MacNamara v. City of New York*, No. 04 Civ. 9216, 2007 WL 1169204, at *1 (S.D.N.Y Apr. 20, 2007) (Francis, J.) (quoting *Tigue v. U.S. Dep't of Justice*, 312 F.3d 70, 76 (2d Cir.2002). "'Purely factual' material is not protected by the privilege." *Id.* (quoting *Grand Central P'ship v. Cuomo*, 166 F.3d 473, 482 (2d Cir. 1999) Moreover, the deliberative process privilege is "qualified and as such must be balanced against a litigant's substantial need for the information in issue." *Id.* at 92.

[6] The U.S. has also pressed the objection that the requested documents are publicly available and/or in NPC's possession. *See, e.g.*, Ex. W at Nos. 71-73, 75-82. That requested documents are publicly-available and/or in the possession of the requesting party is not a valid basis for refusing to produce them. *See Travelers Indemn. v. Northrop Grumman Corp.*, No. 12 Civ. 3040, 2012 WL 6200680 at *2 (S.D.N.Y. Dec. 10, 2012) (ordering production of documents obtained from publicly-available sources); *Davidson v. Goord*, 215 F.R.D. 73, 77 (W.D.N.Y. 2003).

The non-public documents that NPC seeks through these requests concern factual information about the Government's adherence programs—including how they work and are administered—not its deliberations concerning those programs. Such documents are not protected by the deliberative process privilege and, consequently, must be produced. *See id.* at 93 (rejecting claim of deliberative process privilege over memoranda that contained factual material and were not "policy-oriented").[7]

2. The Requested Documents Are Within The States' Control And Must Be Produced

The States have also refused to produce the requested documents on the basis that they are purportedly not in the possession, custody, or control of the Single State Agencies ("SSAs") that administer each State's Medicaid program.[8] Specifically, the States contend that the SSAs, not the States themselves, are the "real parties" to this action and that the SSAs have no obligation to produce documents in the possession of other state agencies. *See, e.g.*, Ex. HH at 1-2.

As a threshold matter, the States cannot now claim that the SSAs—not the States—are the plaintiffs in this case simply to reduce their discovery obligations when they have pled to the contrary.[9] The Government, like any other civil litigant, must abide by the rules of discovery, particularly where, as here, it is the party bringing suit. *See, e.g.*, *Collins & Aikman*, 256 F.R.D.

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[7] To the extent any responsive documents also contain information that is protected by the deliberative process privilege, the Government should furnish a privilege log that sets forth in detail the bases on which it claims the withheld information is "predecisional, deliberative, purely subjective, and neither adopted nor incorporated in the agency's final decision." *S.E.C. v. Collins & Aikman Corp.*, 256 F.R.D. 403, 416 (S.D.N.Y. 2009); *accord* S.D.N.Y. Rule 26.2.

[8] Pursuant to the Social Security Act, each State is required to establish a "single state agency" to administer Medicaid within the State. *See Almenares v. Wyman*, 334 F. Supp. 512, 517 (S.D.N.Y. 1971) (citing 42 U.S.C. §§ 602(a)(3), 1382(a)(3) (1970)).

[9] *See, e.g.*, Dkt. No. 61 at ¶¶ 12-20; Dkt. No. 162 at ¶ 12; Dkt. No. 82 at ¶ 12.

at 414 ("Like any ordinary litigant, the Government must abide by the Federal Rules of Civil Procedure. It is not entitled to special consideration concerning the scope of discovery, especially when it voluntarily initiates an action."). As parties to this case, the States are obligated to produce responsive documents in their possession, custody, or control. This obligation extends to documents that parties have the "legal right or the practical ability to obtain," such that the party "is deemed to have 'control,' even if the documents are actually in the possession of a non-party." *In re Flag Telecom Holdings, Ltd. Sec. Litig.*, 236 F.R.D. 177, 180 (S.D.N.Y. 2006); *accord Shcherbakovskiy v. Da Capo Al Fine, Ltd.*, 490 F.3d 130, 138 (2d Cir. 2007) ("[I]f a party has access and the practical ability to possess documents not available to the party seeking them, production may be required.").

In addition, even if the States were correct (and they are not) that the "real parties" in this case are the SSAs, *see* Ex. HH at 1, their objection would still fail. "[W]hen an agency of government institutes suit, any obligation to disclose relevant information extends to the government qua government requiring disclosure of all documents in its possession, custody or control, not just those materials in the immediate possession of the particular agency-plaintiff." *See, e.g.*, *Compagnie Francaise d'Assurance Pour le Commerce Exteriur v. Phillips Petroleum Co.*, 105 F.R.D. 16, 35 (S.D.N.Y. 1984). Even if the States had to produce only those documents in the possession, custody, or control of the SSAs, the States' production would still be unquestionably insufficient because the States have failed to produce responsive documents over which the SSAs unquestionably have control, including from other state agencies and state-run hospitals. *See* Ex. II.

The SSAs have possession, custody, or control for discovery purposes over documents held by other state entities involved in the administration of Medicaid. The SSAs are tasked with

the far-reaching mission to "[a]dminister or supervise the administration of the plan" as well as "[m]ake rules and regulations that it follows in administering the plan or that are binding upon local agencies that administer the plan." 42 C.F.R. § 431.10(b); 42 U.S.C. § 1396a(a)(5). Federal regulations grant nearly plenary authority to the SSAs to control the administration of Medicaid. *See, e.g.*, 42 C.F.R. § 430.0 (authorizing the SSAs to administer all aspects of the Medicaid program, including determining eligibility, the types and range of services, payment levels for services, and administrative and operating procedures); *see also* 42 C.F.R. § 431.10(e) (noting that the SSAs "may not delegate . . . the authority to supervise the plan or to develop or issue policies, rules, and regulations on program matters"). This expansive grant of authority alone negates any claim that the SSAs are unable to obtain documents from state entities that provide Medicaid services. *See Emily Q. v. Bonta,* 208 F. Supp. 2d 1078, 1093 (C.D. Cal. 2001) (noting that state entities participating in Medicaid in California "must comply with any decision of DHS [California's SSA]," and finding that those agencies "are subject to the 'control' of DHS in the administration of Medicaid"). Moreover, since "[p]ayments for services are made directly by the State to the individuals or entities that furnish the services," the SSAs necessarily have possession, custody, or control over Medicaid documents concerning the services rendered by such entities. *See* 42 C.F.R. § 430.0; *see also* 42 C.F.R. § 447.202 ("The Medicaid agency must assure appropriate audit of records if payment is based on costs of services or on a fee plus cost of materials."). In addition, federal regulations require the SSAs to maintain or supervise the maintenance of extensive records and periodically submit that information to the federal government, and the SSAs necessarily obtain that information from the state entities involved in the administration of Medicaid as part of this task. *See, e.g.*, 42 C.F.R. §§ 431.16-431.17; Ex. JJ, Centers for Medicare & Medicaid Servs., Medicaid Data Sources–

General Information, *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/MedicaidDataSourcesGenInfo/index.html (explaining that Medicaid data is based on periodic reports and the collection of program and financial data from the States). Thus, in light of their broad administrative authority and reporting requirements, the SSAs cannot legitimately claim that they lack possession, custody, or control over documents held by other state entities that participate in Medicaid, such as State Hospitals.

* * *

Because the documents sought by RFP Nos. 71-73, 75-82, and 89-92 to the U.S., RFP Nos. 36 and 38-39 to the States, and RFP No. 50 to California are relevant and reasonably calculated to lead to the discovery of admissible evidence, and because the Government offers no valid objection to their production, the U.S. and the States should be compelled to produce all non-privileged documents responsive to these discovery requests.

II. THE GOVERNMENT SHOULD BE ORDERED TO PRODUCE DOCUMENTS RELATING TO ITS IMMUNOSUPPRESSIVE THERAPIES FOR KIDNEY TRANSPLANT PATIENTS AND ITS IRON CHELATION THERAPIES

NPC has also sought, and the Government has refused to provide, documents relating to immunosuppressive therapy for kidney transplant patients and iron chelation therapy for patients in hospitals and medical facilities operated by the U.S., and the identities of HCPs at Veterans Affairs ("VA") hospitals who make prescribing decisions for patients after kidney transplant surgery. RFP Nos. 19, 94-97, and 99 and Interrogatory No. 9 to the U.S. seek:

- Documents reflecting or relating to any treatment protocols for kidney transplants and iron chelation therapy performed at federally operated healthcare facilities (RFP Nos. 19, 99);
- Documents relating to the administration of Exjade or the promotion of Exjade treatment adherence developed by certain federal agencies or provided by HCPs at VA facilities (RFP Nos. 94- 97); and

- The identities of "any [provider of healthcare services] at a VA Hospital who makes prescribing decisions of appropriate medications for patients after kidney transplant surgery" (Interrogatory No. 9).

See Ex. KK at No. 19; Ex. J at Nos. 94-97, 99; Ex. LL at No. 9. NPC issued similar requests to the States for Exjade and iron chelation therapy treatment protocols developed by the States. *See* Exs. K-U at Nos. 37, 44, 46; Ex. V at No. 51.

Other than the States' objection that the States are obligated to produce only documents within the custody, possession or control of the SSAs, and the Government's objections on deliberative process grounds, both of which fail for the reasons set forth in Section I.B, *supra*, the Government appears to be withholding responsive documents and a substantive interrogatory response based only on its objection that the discovery sought is not relevant. *See* Ex. MM at No. 19; Ex. X at Nos. 94-97, 99; Ex. Z at 3-4; Ex. AA; Ex. NN at 4; Ex. OO at 5; Exs. BB & CC at Nos. 37, 44, 46; Ex. DD at No. 51. Here too, the Government's own claims and arguments have made this information relevant and discoverable.

The documents and information sought through these discovery requests are plainly relevant to the Government's claims that specialty pharmacies were improperly suggesting that transplant physicians "switch" patients to Myfortic, or improperly convincing patients to resume Exjade therapies for financial, non-clinical reasons. For example, with respect to Myfortic, when the Court questioned whether transplant surgeons were "complete pushovers" that "would do anything that the pharmacists said," the Government argued that the pharmacy recommendations "were made under the pretext of certain clinical justifications, and the result was in many cases that patients were switched from a competing drug to Myfortic." Ex. B at 8:21-9:3; *accord* Second Am. Compl. ¶ 148 (alleging that specialty pharmacy's faxed recommendations to physicians to switch patients to Myfortic were "presented . . . as an exercise in clinical judgment" but were in fact made "entirely as a matter of economic calculation"). Asked whether

these switches were made to the patients' detriment, the Government indicated that they were because "there is generally some risk whenever patients, as we understand it, switch from one drug to another." *Id.* at 9:4-8.

The clinical considerations the Government argues were "pretext[ual]" relate to findings that Myfortic has important advantages for certain patient populations. Myfortic's branded competitor, CellCept, and its generic forms are metabolized in the stomach, which may cause gastrointestinal problems. In contrast, Myfortic is enteric-coated, permitting it to pass through the stomach to metabolize in the small intestine, and therefore, may cause fewer gastrointestinal complications than CellCept and generic MMF. In addition, proton pump inhibitors ("PPIs"), such as Prilosec®, Prevacid®, and Nexium®, which are now available over-the-counter, and are often taken by patients suffering from gastrointestinal disorders, can interfere with the absorption of CellCept's active ingredient.[10] However, Myfortic is not rendered less effective by PPIs.[11]

The requested documents bear directly on the plausibility of the Government's allegations that the clinical justifications for switching patients to Myfortic were pretextual. For example, if a kidney transplant treatment document from a VA hospital indicates that patients reporting gastrointestinal complications while taking CellCept or generic MMF should be switched to Myfortic, or that patients taking PPIs should be switched to Myfortic, these facts would substantially undermine the U.S.'s contention that the alleged "switches" to Myfortic were the result of the efforts of financially incentivized pharmacists rather than the independent

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[10] *See, e.g.*, Ex. PP, U.S. Dep't of Health & Human Servs., U.S. Food and Drug Admin., "CellCept (mycophenolate mofetil) Capsules, Tablets, Oral Suspension and CellCept (mycophenolate mofetil hydrochloride) for injection" (last updated Nov. 1, 2013) at 2 ("PPIs should be used with caution when coadministered to transplant patients being treated with CellCept."), *available at* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm310868.htm.

[11] *See, e.g.*, Ex. QQ, CellCept Label approved September 27, 2013, at 21.

medical judgment—based on valid clinical considerations—of prescribing HCPs. *See, e.g.*, Second Am. Compl. ¶¶ 6, 148, 188. Additionally, documents in the possession of the U.S. indicating that HCPs at Government hospitals switched patients to Myfortic for independent clinical reasons and without a recommendation from any specialty pharmacy would undermine the U.S.'s allegations of improper "switching" as part of the purported NPC kickback scheme.

Similarly, the identities of the HCPs at VA hospitals who prescribe immunosuppressants following kidney transplant surgery will permit NPC to identify HCPs it may wish to interview or depose regarding the factors that influence their immunosuppressant prescribing decisions. Facts indicating that the U.S.'s own HCPs made prescribing decisions similar to the ones it contends in the Amended Complaint were influenced by purported kickbacks are relevant to the U.S.'s theory that the specialty pharmacies were using "pretext[ual]" clinical reasons to convince physicians to switch patients to Myfortic.

With respect to Exjade, the Government and the Relator have argued to the Court that incentivizing BioScrip to promote Exjade adherence was somehow improper because Exjade is a medication that iron overload patients should only take after transfusions and "for a short period of time," on an as-needed basis. *See, e.g.*, Ex. B at 26:6-13, 29:19-30:4. Documents showing that the Government's patient guides and protocols for treating iron overload include prescribing Exjade and encouraging adherence to an Exjade treatment therapy are relevant to disproving the allegation that BioScrip's adherence efforts were improper. *See, e.g.*, Second Am. Compl. ¶¶ 259-60. Similarly, protocols indicating that Exjade treatment and/or iron chelation therapies should be undertaken consistently, rather than only on an "as-needed" basis as deemed by the patient, is relevant to disproving the Government's claim that doctors want their patients to take

Exjade only when they were undergoing transfusions or actually feeling the effects of iron overload. *See* Ex. B at 26:6-13.

Finally, the Government has alleged that "Novartis and BioScrip were aware that nearly all the BioScrip employees assigned to 'counsel' Exjade patients lacked the clinical knowledge or patient information to provide appropriate counseling to patients regarding Exjade." *See* Second Am. Compl. ¶ 228. Because of this and other Government contentions that NPC's use of BioScrip to distribute Exjade was inappropriate, NPC requested documents regarding the Government's use of BioScrip, specifically the VA's use of BioScrip to dispense Exjade to its patients, which NPC believes to have been the case based on BioScrip's representations to NPC personnel. Ex. J at No. 94. The Government refuses to produce that information. Ex. X at No. 94. The documents NPC seeks regarding the Government's selection or designation, whether official or unofficial, of BioScrip as a pharmacy to dispense Exjade or other medications related to iron chelation therapy are relevant to the validity of the Government's allegation that BioScrip was unqualified to provide appropriate counseling to patients regarding Exjade and the ability of outside entities, such as NPC or the Government, to make that assessment.

NPC's ability to effectively defend against the Government's "switching" and kickback allegations will be prejudiced if it is unable to obtain discovery of the extent to which the Government itself—through federal and State hospitals and agencies—endorses Exjade adherence and Myfortic based on clinical reasons, or approved of BioScrip as a qualified Exjade provider. The relevance objections to RFP Nos. 19, 94-97, and 99, and Interrogatory No. 9 to the U.S., RFP Nos. 37, 44, and 46 to the States, and RFP No. 51 to California, are baseless, and the Government should be compelled to produce all non-privileged documents responsive to these RFPs and respond completely to the interrogatory.

III. THE GOVERNMENT SHOULD BE COMPELLED TO PRODUCE ITS COMMUNICATIONS WITH BIOSCRIP REGARDING BIOSCRIP'S STIPULATIONS OF FACT

On January 6, 2014, the U.S. and BioScrip entered into a Settlement Agreement and Stipulation pursuant to which BioScrip stipulated to certain alleged facts relating to the Government's Exajde-related allegations. *See* Ex. RR, Dkt. No. 41, at 3-7. The States entered into similar settlement agreements with BioScrip. *See, e.g.*, Ex. SS, Dkt. No. 127-1; Ex. TT, Dkt. No. 129-1.

NPC served document requests on the Government seeking documents relating to its settlement agreements with BioScrip, including the agreements themselves, any documents reflecting any communications relating to such agreements, and any related admissions or acknowledgements of facts. *See* Ex. J at No. 85; Exs. K-U at No. 42. Although the U.S. agreed to produce responsive documents "to the extent that such documents are relevant to the claims or defenses asserted in this action and are not otherwise [privileged]," *see* Ex. X at No. 85, it ultimately has not produced *any* documents responsive to this request, contending that all of the requested documents are privileged and/or not relevant. The States initially refused to produce any responsive documents, objecting primarily on the grounds of privilege and relevance. *See* Exs. BB & CC at No. 42. The States subsequently agreed to produce the settlement agreements as well as the same types of documents that the U.S. agreed to produce to NPC. *See* Ex. HH at 4; Ex. FF at 3.

In an attempt to resolve this dispute without motion practice, Sheth Decl. ¶ 51, NPC agreed to the Government's proposal that it would produce its communications with BioScrip about the admissions of fact if NPC would not seek to depose the Government's attorneys regarding the settlement. *See* Ex. UU at 2. After NPC acquiesced to the Government's demand, however, *BioScrip* sought to condition the *Government's* compliance with NPC's discovery

requests on a similar concession for *BioScrip's* attorneys. *See id.* Given the possible need for such discovery from these very differently situated percipient witnesses, NPC did not accede to BioScrip's demand. *See id.* at 1-2. Unfortunately, notwithstanding its prior agreement to produce, the Government has followed BioScrip's instruction that it withhold these responsive, non-privileged documents while BioScrip attempts to extract this additional concession from NPC. *See id.*; Ex. VV. There can be no question that the Government cannot withhold relevant, non-privileged documents simply because BioScrip asks it to do so. *See, e.g.*, *Keaton v. Hannum*, No. 1:12-cv-00641, 2013 WL 1818993, at *4 (S.D. Ind. Apr. 29, 2013) ("The Court is unaware of any basis for [a party] to refuse to produce documents in her possession because a non-party to this case may have an objection to their production, but that party has not intervened or sought a protective order to prevent their disclosure.").[12]

In any event, there can be no question that the requested documents are relevant to the claims and defenses in this case. BioScrip's stipulation encompasses numerous stipulated facts, including that NPC "provided input on aspect of . . . how to discuss potential side effects with Exjade patients"; "approved" BioScrip's call scripts; and "increased rebates that BioScrip earned for each Exjade shipment . . . in order to encourage BioScrip to continue the efforts of its Exjade Team." *See* Ex. RR, Dkt. No. 41 at (l), (p) & 3-7. The Government has repeatedly invoked these stipulated facts to support their claims against NPC. *See, e.g.*, Ex. B at 28:5-10 (counsel for U.S. citing BioScrip's stipulation to explain NPC's alleged scheme to induce BioScrip to

[12] This recent turn of events is particularly concerning given that *BioScrip* initially agreed to produce the same documents in response to a third party subpoena *but for* the *Government's* objection to their production. *See* Ex. AAA at 2; *see also* Exs. WW–ZZ. BioScrip later reversed course, claiming that NPC should obtain the documents from the Government directly through party discovery for alleged burden reasons, and NPC decided to pursue its requests with the Government instead. Now that the Government has otherwise agreed to produce the documents in response to party discovery, BioScrip is obstructing the documents' production.

directly contact patients to "push" Exjade refills); Second Am. Compl. ¶¶ 245, 299 (complaint allegations tracking BioScrip's stipulated facts); California Second Amended Complaint-In-Intervention, Dkt. No. 162 ¶¶ 56, 110 (same); Ex. BBB (DOJ press release touting BioScrip stipulations). Communications regarding these stipulated "facts," which relate to the Government's key allegations regarding Exjade, could provide substantial insight into what BioScrip was—and, even more importantly, was not—willing to stipulate to in connection with the purported kickback scheme as well as what revisions the Government wanted incorporated into those "facts."

No privilege applies to preclude discovery of these materials. Federal Rule of Evidence 408—the "settlement privilege"—does not shield these communications from production because it "pertains only to evidentiary issues at trial, and does not govern pretrial disclosure of settlement agreements. Rather, Federal Rule of Civil Procedure 26(b)(1) sets the standard for pretrial disclosure, and requires only that the information sought be relevant and calculated to lead to the discovery of admissible evidence." *Conopco, Inc. v. Wein*, No. 05-civ-9899, 2007 WL 1040676, at * 5 (S.D.N.Y. Apr. 4 2007); *see also In re Initial Pub. Offering Sec. Litig.*, No. 21 MC 92, 2004 WL 60290, at *2 (S.D.N.Y. Jan. 12, 2004) ("[T]he discovery of settlement materials is not governed by a different standard than other documents under the Federal Rules of Civil Procedure. Because plaintiffs have made the minimal showing of relevance required under the Rules, they are entitled to discovery"); *id.* at *4 ("Rule [26] specifically permits discovery of inadmissible information, so long as that information may lead to the discovery of admissible evidence. Thus, admissibility is not a prerequisite to discoverability, and the scope of relevance under Rule 26 is broader than under the Rules of Evidence.").

Nor are the documents subject to any attorney-client or work product privilege because they consist of communications between the Government, on the one hand, and a third party, BioScrip, on the other. Having waived any potential privilege claim by including BioScrip in these communications,[13] the Government cannot refuse production on privilege grounds. *See, e.g.*, *Schanfield v. Sojitz Corp. of Am.*, 258 F.R.D. 211, 214 (S.D.N.Y. 2009) (Francis, J.) ("It is well-established that voluntary disclosure of confidential material to a third party waives any applicable attorney-client privilege.").

Because the requested documents are unquestionably relevant and not privileged, the Government should be compelled to produce its settlement communications without further delay.

[13] To the extent the Government possesses purely internal, privileged communications *reflecting* these settlement communications, those communications should be redacted, logged and produced to the extent they also contain non-privileged material (such as the settlement communications themselves).

CONCLUSION

For all of the foregoing reasons, NPC respectfully requests that the Court grant NPC's motion to compel in its entirety.

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Respectfully submitted,

/s/ Manisha M. Sheth
Faith E. Gay
Manisha M. Sheth
QUINN EMANUEL URQUHART & SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
Tel. No.: 212-849-7000

Evan R. Chesler
Rachel G. Skaistis
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019
Tel. No.: 212-474-1000

Michael A. Rogoff
Manvin Mayell
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. No.: 212-836-8000

Counsel for Defendant
Novartis Pharmaceuticals Corporation